

**REMARKS**

The Examiner is thanked for the thorough and professional Office Action and the detailed explanation in the rejections. Pursuant to that Office Action, Claims 1 and 5 have been amended to more definitely set forth the invention and obviate the rejections. In addition, new Claims 6 and 7 are presented. Support for new Claims 6 and 7 can be found in the original claims. This amendment is being submitted in the revised format published in the Official Gazette on February 25, 2003 and posted on the office website. The present amendment is deemed not to introduce new matter. Claims 1-7 are in the application.

Reconsideration is respectfully requested of the objection to the Specification. The portions of the Specification containing the term "zelatin" have been corrected and reference to the Japanese priority document has also been included. It is therefore believed that the rejection is now moot. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the objection to Claim 1. Claims 1 and 5 have been amended to correct spelling and it is therefore believed that the rejection is now moot. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1 and 5 under 35 U.S.C. §102(a) as being anticipated by Sakai Yasuo (JP 07082299).

The named inventor of this Japanese patent is the inventor of

the present application. In this Japanese patent, a peptide having a molecular weight of less than 1,000 Da is nonantigenic, but has only a lower effect as a stabilizer. The peptide in JP 07082299 does not act sufficiently as a stabilizer. In the abstract of Bio. Bull., 21(4), 330-334, 1998 of the inventor, Yasuo Sakai, "FreAlagin P (M.W. 200-500)" comprising peptide of less than M.W. 1,000 is excluded from the stabilizers. It is therefore respectfully submitted that the Yasuo reference (JP 07082299) does not anticipate or render unpatentably obvious the nonantigenic stabilizer now called for in the claims herein.

Moreover, no use of the peptide composition shown by the inventors in Japanese Patent Application Laid-Open No. 7-82299 as a stabilizer was anticipated since the gelatin whose molecular weight of not more than about 10,000 was conventionally thought to have little stabilizing effects of urokinase as shown in Japanese Patent Application Laid-Open No. 54-80406.

Additionally, the peptide composition shown in Japanese Patent Application Laid-Open No. 7-82299 also had a problem of the limitation in raising the yield due to the narrow range of molecular weight (see page 2, line 27, to page 3, line 5 of the Specification). Consequently, the peptide disclosed in 7-82299 was not used as a stabilizer since one of ordinary skill in the art would not think that the peptide of 7-82299 was a stabilizer. It is pointed out that this application is based on a Japanese Patent Application No. 7-352918 filed on December 27, 1995 and is now

issued as Japanese Patent No. 3343712 on August 30, 2002. This Japanese patent also contains the same Claim 1 as in the present application. The Japanese application 7-82299 was laid-open on March 28, 1995 and Japanese Application No. 7-352918 was filed within one year after Japanese Patent Application 7-82299.

In addition, whether the molecular weight is 1,000 or 2,000 is important for the yield and it is important whether the peptide is known as a stabilizer or not. In the present case, it can be seen from the foregoing that the prior work by Mr. Yasuo in JP 007082299 did not produce the peptide which was both nonantigenic and acted as a stabilizer. For this reason, it is respectfully submitted that this reference neither anticipates nor renders unpatentably obvious the subject matter called for in Claims 1 and 5 herein.

The Examiner recognizes that the Sakai Yasuo reference does not disclose that the nonantigenic peptide is obtained by gel filtration or by reverse phase chromatography but bases the rejection of Claim 5 (product by process) on the In re Thorpe case in which a known product was made according to the prior art processes. In this particular case, the precise structure of the nonantigenic stabilizer of the present invention is not entirely known. That is the reason the product is claimed using a product by process. Therefore, it is believed that the reliance upon In re Thorpe is misplaced since it is concerned only with well-known processes used to produce a known product. In this case the product is not known in the prior art and certainly not known in

the Yasuo JP 7-082299 which was invented by the same inventor of the present application. For these and the numerous reasons discussed above, it is respectfully submitted that this rejection fails. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1 and 5 under 35 U.S.C. § 102(b) as anticipated by Quelle, German Patent No. 4244418A1.

As the Examiner recognizes, the Quelle patent does not disclose a nonantigenic peptide which also acts as a stabilizer. Moreover, the Examiner has recognized in the office action that Quelle differs from the instant invention by not decomposing the composition by column processes and by not purifying the composition by gel filtration or reverse phase chromatography.

It is therefore obvious that the Quelle reference produces a peptide in an entirely different manner than the peptide of the present invention. This, of course, would account for the difference in structure and the properties unexpectedly obtained by the inventor herein.

It is also noted that the Examiner mentions that Quelle does not teach the molecular weight or the peptide range from 20,000 Da, and speculates that the claimed peptide appears to be the same as the prior art. It is respectfully submitted that there is no room for this type of speculation especially where the inventor of the present application has demonstrated in other literature and in

patents the nature of the peptide process.

It is respectfully submitted that applicant has amply demonstrated the nonantigenic and stabilizing effect of the composition of the present invention which is nowhere disclosed in the Quelle reference. In this regard, it is respectfully submitted that it is the burden of the Examiner to demonstrate that the Quelle reference anticipates or renders unpatentably obvious the subject matter called for in the claims herein. In this connection, it is respectfully submitted that the office has not met its burden in this regard and, therefore, this rejection fails as a matter of law. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claim 5 under 35 U.S.C. § 102(b) as anticipated by Thakur, et al.

In the Thakur, et al. reference, the model nucleus (mn): the product is chemically bonded with AHA (aminohexanoic acid), AHA-Lys-Lys-Gly-OPEG, etc. Moreover, (2) this product is three peptide chains and (3) the product has a cubic triple-helix structure due to (1) or (2).

Further, in this product, a transition temperature similar to native collagen is observed due to this cubic triple helix structure.

In contrast, in the present invention, (1) the stabilizer peptide is not bonded with any compound and, (2) the stabilizer peptide is only one peptide chain, and (3) the peptide does not

have a triple-helix structure. Further, in the peptide, the transition temperature is not observed. Most importantly, the peptide is nonantigenic and a stabilizer.

It is therefore respectfully submitted that the stabilizers of the present invention clearly distinguish from those disclosed in the Thakur, et al. reference. Consequently, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over Sakai Yasuo in view of "Current Protocols in Molecular Biology (Vol. 2, Chapter 10, pages 10.1.1-10.18.6, 1990) or Quelle (German Patent No. 4244418A1) in view of "Current Protocols in Molecular Biology" (Vol. 2, Chapter 10, pages 10.1.1-10.18.6, 1990).

Both the Yasuo Japanese Patent and the Quelle German patent are discussed above. In the rejection the Examiner has recognized that the Yasuo and Quelle references differ from the present invention by not decomposing the composition by column process and by not purifying the composition by gel filtration or reverse phase chromatography. Nonetheless, the Examiner indicates that column processes and reverse phase chromatography are standard procedures and the gel filtration is also a common procedure known in the art.

A formula is not the compound nor what is patented. Patentability is not, therefore, dependent solely on the similarity of the formula of the claimed compound to that of a prior art

compound. The unobviousness of its properties must also be considered. In re Papesch, 137 USPQ 43 (CCPA, 1963). Once a property of a compound has been proved, it is a relevant portion of the invention as a whole and must be considered in determining the issue of obviousness under 35 U.S.C. § 103. In re Lunsford, 148 USPQ 716 (CCPA, 1966).

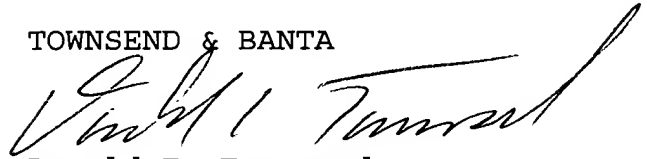
In the present case, it is respectfully submitted that the applicant herein has established that the peptide of the present invention has both nonantigenic and stabilizer properties which was nowhere disclosed in the prior art. Having established this property, the Examiner must consider this in determining the issue of obviousness under 35 U.S.C. § 103 in view of the above-cited authority. In this particular case, it is apparent that the Examiner has not considered this unexpected property obtained using the process of the present invention to obtain this particular peptide. Consequently, this rejection fails, as a matter of law, in view of the above authority. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

DOCKET NO. SUD-001-USA-CIP

Respectfully submitted

TOWNSEND & BANTA

A handwritten signature in black ink, appearing to read "Donald E. Townsend", written in a cursive style.

Donald E. Townsend  
Reg. No. 22,069

TOWNSEND & BANTA  
1225 Eye Street, N.W.  
Suite 500, #50028  
Washington, D.C. 20005  
(202) 682-4727

Date: March 5, 2003



**CERTIFICATE OF MAILING**

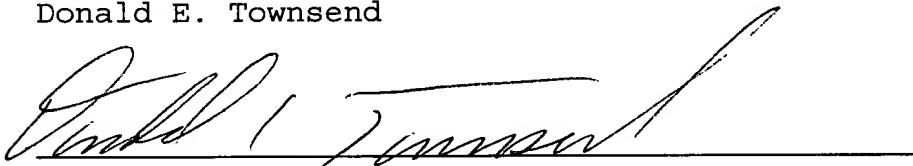
I hereby certify that this amendment, transmittal and check for \$42.00 and Petition For Extension of Time and Check in the amount of \$465.00 in Docket No. SUD-001-USA-CIP, Serial No. 09/849,395, filed on May 7, 2001 is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents

Washington, D.C 20231

on March 5, 2003

Donald E. Townsend

A handwritten signature in cursive script, appearing to read "Donald E. Townsend", is written over a horizontal line.